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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

TYLER WOOD,	)	Case No. 6:14-cv-06298-CJS
Plaintiff,	)	**OPPOSITION TO DEFENDANT'S MOTION TO DISMISS**
vs.	)	**&**
MEDTRONIC, INC.,	)	**MOTION FOR LEAVE TO AMEND COMPLAINT**
Defendant.	)	

COMES NOW Tyler Wood ("Plaintiff"), by his attorney, Thomas J. Rzepka, and prays for the relief detailed hereafter.

I. OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

In response to Defendant's Motion to Dismiss filed on January 30, 2015, Plaintiff submits the following opposition. In its motion, Defendant alleges: (1) Plaintiff's Complaint is subject to dismissal under Rule 12(b)(6) of the Federal Rules of Civil Procedure; (2) Plaintiff fails to comply with the particularity requirements for fraud pleadings pursuant to Rule 9(b); (3) Plaintiff's claims are expressly preempted by the Medical Device Amendments of 1976; (4) Plaintiff's claims are impliedly preempted under *Beckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 344 (2001); (5) Plaintiff's claims are prohibited by the "no private right of action" provision of the Federal Food, Drug and Cosmetic Act; and (6) in the alternative, Plaintiff's claims fail on independent state-law grounds, including the learned intermediary doctrine, comment (k) to the Restatement (Second) of Torts, and third-party reliance being insufficient to properly claim common law fraud.

Plaintiff herein addresses each of these points of authority in turn.

A. LEGAL STANDARD

In considering a motion to dismiss for failure to state a claim pursuant to Rule 12 (b)(6), a court must accept all factual allegations in the complaint as true and make all reasonable inferences in a plaintiffs' favor. *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007). In order to survive such a motion, a complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009), quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007); *ATSI Commc'ns, Inc.*, 493 F.3d at 98. This assumption of truth applies only to factual allegations and is inapplicable to legal conclusions. *Ashcroft*, 556 S.Ct. at 1949.

"A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft*, 129 S.Ct. At 1949. In making its determination, a court is entitled to consider, as relevant here:

> (1) facts alleged in the complaint and documents attached to it or incorporated in it by reference, (2) documents 'integral' to the complaint and relied upon in it, even if not attached or incorporated by reference, (3) documents or information contained in defendant's motion papers if plaintiff has knowledge or possession of the material and relied on it in framing the complaint, (4) . . . , and (5) facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence.

In re Merrill Lynch & Co., Inc., 273 F.Supp.2d 351, 356-357 (S.D.N.Y. 2003) (citations omitted), *aff'd* 396 F.3d 161 (2d Cir. 2005), *cert. denied* 546 U.S. 935 (2005); *see Weiss v. Inc. Vill. of Sag Harbor*, 762 F. Supp. 2d 560, 567 (E.D.N.Y. 2011).

B. ARGUMENT

1. Plaintiff's Claim Should Not Be Dismissed for Failure to State a Claim when Amending the Complaint Would Cure Any Deficiencies

First and foremost, Plaintiff's claim should not be dismissed where the Court could allow Plaintiff to amend the original Complaint to cure any deficiencies alluded to in Defendant's Motion.

Defendant alleges Plaintiff's Complaint must be dismissed because it "fails to comply with federal pleading standards" and "offers no well-pleaded factual allegations showing what representations Medtronic supposedly made about the Infuse device, when and where those representations appeared, or how Plaintiff or his physicians because aware of and relied upon those statements." (Def.'s Mot., at 2.) Defendant also claims "[t]here are no allegations identifying any particular facts that Medtronic knew but did not disclose" and that this absence unfairly deprives Medtronic of the opportunity to present a meaningful response." (*Id.*)

The purposes of a complaint as contemplated by Rule 8 is to give Defendant fair notice of the nature of Plaintiff's claim against it and of stating a claim for relief that is "plausible on its face" as required by *Iqbal* and *Twombly*. Pleadings are meant to "focus litigation on the merits of a case rather than on technicalities that might keep plaintiffs out of court." *Swierkiewicz v. Sorema N.A.*, 524 U.S. 506, 514, 122 S.Ct. 992, 152 L.Ed.2d 1 (2002).

Here, Plaintiff's Complaint should not be dismissed in the interest of justice, where the Court could instead grant Plaintiff leave to file an amended complaint in order to cure the deficiencies which Defendant has identified in its Motion. In fact, the Proposed First Amended Complaint attached herein will do well to quell any of Defendant's concerns regarding meeting the federal pleading standards, as well as allow the Court to narrow its focus on the merits of Defendant's Motion as opposed to the procedural sufficiency of Plaintiff's pleadings. Plaintiff is, in fact, requesting such relief below, and further authority and justification is presented therein.

Specifically, Defendant alleges the original Complaint fails to: (1) allege facts showing off-label promotion; (2) allege facts showing a failure to warn; (3) identify any design or manufacturing defect; and (4) plead fraud with particularity. (Def.'s Mot., at 10-15.) If the Court inspects the Proposed First Amended Complaint ("FAC") attached as Exhibit A, it may well agree that the deficiencies stated above have been more than cured by the amendment in that the facts supporting each and every allegation have been bolstered and will, in their current state, more than survive federal pleading standards.

Defendant is mistaken in believing that Plaintiff must show his entire hand at this early stage of the case, as further information must be acquired through the discovery process. The specific facts regarding the misrepresentations and material omissions made by Defendant in order to induce Plaintiff and his physician to elect to use Defendant's product despite its

associated relative dangers and risks of injury are enough to satisfy federal pleading standards and present a prima facie case to the Court. The factual circumstances presented in Plaintiff's Proposed First Amended Complaint are such that any court or jury could glean from them serious violations of the law which were the direct and proximate result of Plaintiff's severe injuries. The causal connection between Defendant's misrepresentations and its subsequent failure to warn, Plaintiff's physician's treatment recommendation, and Plaintiff's resulting injuries is made abundantly clear in the Proposed FAC attached herein.

Specifically with regard to Defendant's claim that the original Complaint fails to plead fraud with the particularity required by Rule 9(b), the Proposed FAC outlines very specific factual circumstances which provide the Court with sufficient information to rely on Plaintiff's representations regarding Defendant's off-label promotion to opinion leaders, the subsequent DOJ investigation, and the two qui tam actions against Defendant. The terms of the Settlement Agreement reached thereafter required Defendant to disclose the circumstances for each of those promotional efforts identified by the DOJ, but Defendant has failed to provide that information to the public, thus preventing Plaintiff from pleading that fraud with particularity.

Judge Melloy, in his dissenting opinion in *Medtronic Leads*, recognized the relative difficulty — rising to level of practical impossibility — of any plaintiff being able to plead specific violations of federal law revolving around the FDA's PMA process. He recognized that, if required to plead these specific facts with sufficient particularity before discovery, "it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion," and that in analyzing the sufficiency of pleadings, "a plaintiff's pleading burden should be commensurate with the amount of information available to them." *See In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200, 1212 (8th Cir. 2010) (Melloy, J., dissenting).

Plaintiff submits that, with the factual support provided in the Proposed FAC, he has pled sufficiently given the amount of information to which he has access. However, if the Court allowed Plaintiff to acquire those records in order to bolster its Proposed FAC, such particularity could be achieved. Until then, the factual circumstances plead in the Proposed FAC encompass the entirety of the information made publicly available and thus the Court should not dismiss

Plaintiff's fraud claim as a result of specific facts purposefully made unavailable by Defendant in connection with another action against the United States Government.

Accordingly, as these deficiencies identified by Defendant in its Motion to Dismiss can be cured by granting leave to amend Plaintiff's original Complaint, the Court should deny the portion of Defendant's motion which is predicated on Plaintiff's failure to state a claim.

2. Preemption Protection for PMA Device Manufacturers is Limited

Next, Defendant alleges that Plaintiff's claims are expressly preempted by § 360k.

Infuse is considered a "Class III Medical Device" under the federal Food, Drug, and Cosmetic Act ("FDCA"). Class III medical devices are used "in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" and those that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(c). Under the FDCA, the Food and Drug Administration ("FDA") places new Class III medical devices under a meticulous federal safety and efficacy screening deemed "premarket approval ["PMA"]." *See* 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-20,128 S.Ct. 999, 169 L.Ed.2d 892 (2008).

Furthermore, the Medical Device Amendments of 1976 to FDCA include a limited express preemption clause for product liability claims against manufacturers of Class III medical devices. Specifically, the FDCA states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement — (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) *which relates to the safety or effectiveness of the device* or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).

The Supreme Court has contemplated the issues presented by plaintiffs bringing suit against medical device manufacturers who have premarket approval, ruling in each case that state lawsuits are not preempted by federal law where they are premised on state law theories of defective and unreasonably dangerous design and failure to use reasonable care in the device's design, manufacture, assembly, and sale. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 481, 494-95,116 S.Ct. 2240, 135 L.Ed.2d 700 (1996); *Riegel*, 552 U.S. at 330, 128 S.Ct. 999.

In *Lohr*, the plaintiff brought suit against Defendant for violations of federal regulations in connection with the manufacture of pacemaker leads. *Lohr*, 518 U.S. at 481. The Court held that 21 U.S.C. § 360k(a) does not preempt lawsuits brought against medical device manufacturers who gain premarket approval where the suit is predicated on state law theories, explaining that claims made under state common law based upon a defendant's violation of federal law are not limited by express federal preemption. *Id.* at 495. Specifically, the Court stated:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements. Even if it may be necessary as a matter of Florida law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader, than the federal requirement. While such a narrower requirement might be "different from" the federal rules in a literal sense, such a difference would surely provide a strange reason for finding pre-emption of a state rule insofar as it duplicates the federal rule. The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Lohr, 518 U.S. at 495, 116 S.Ct. 2240. The Court clarified by holding that § 360k(a) does not preempt state rules that merely duplicate federal requirements, and ultimately reversed the District Court's dismissal of plaintiff's complaint. *Id.*

More than a decade later, the *Riegel* Court complicated the PMA preemption landscape with its 2008 ruling affirming the dismissal of the plaintiffs' claims based upon state requirements to be different from or in addition to the federal requirements imposed by the FDA and thus were preempted under § 360k.

In *Riegel*, the plaintiffs claimed that a medical device designed, labeled, and manufactured by Defendant breached state common law duties causing the plaintiffs severe and permanent injury. 552 U.S. at 320, 128 S.Ct. 999. The district court dismissed nearly the entirety of plaintiffs' complaint based upon the express preemption of the claims predicated upon strict liability, breach of implied warranty, negligence in design, and negligence in

manufacturing. *Id.* at 321. However, the lower court found that the plaintiffs' claims dealing with negligent manufacturing where it was based upon Defendant's failure to comply with federal standards and the resulting breach of an express warranty, finding that these claims were not, in fact, preempted by § 360k. *Id.*

The Supreme Court held that the PMA process triggers preemption pursuant to § 360k, reasoning that more restrictive state tort laws requiring a manufacturer's device to be safer than that approved by the FDA would "disrupt[] the federal scheme no less than state regulatory law to the same effect." *Id.* at 325. However, the Court, although ruling in favor of the Defendant in *Riegel*, gave clear instructions to lower courts while limiting its holding to claims where the plaintiff alleges the device "violated state tort law notwithstanding compliance with the relevant federal requirements." *Id.* at 330. Specifically, the Court stated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* In effect, the Court provided that the express preemption provisions of § 360k does not extend protection to medical device manufacturers from liability where the plaintiff's claim is predicated on a violation of federal law — essentially, where the state law is "parallel" to federal law.

Since *Lohr* and *Riegel*, there have been a number of cases litigated based upon those clear instructions made by the Supreme Court to the lower courts. *See, e.g., Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010) (holding that plaintiff's claims are not expressly preempted by federal law to the extent they are based on defendant's violations of federal law); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488-89 (7th Cir. 2005) (holding that state requirements are not expressly preempted where the requirements are "genuinely equivalent"); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248 (7th Cir. 1997) (MDA did not preempt state law claim based on manufacturing defect resulting from violation of FDA requirements); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997) (negligent claims not preempted if claims predicated on failure to adhere to FDA standards in the PMA process); *Howard v. Sulzer Orthopedics, Inc.*,382 Fed.Appx. 436 (6th Cir. 2010) (unpublished opinion); *Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830, 832 (S.D.Ind. 2009); *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 (E.D.Cal. Jul. 9, 2009); *Horowitz v. Stryker Corp.*, 613 F.Supp.2d 271 (E.D.N.Y. 2009); *Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D.Tex. Aug. 13, 2008); *Rollins v. St. Jude Medical*, 583

F.Supp.2d 790 (W.D.La. 2008); *Walker v. Medtronic, Inc.*, 2008 WL 4186854 (S.D.W.Va. Sep. 9, 2008).

Comparing the above rulings — along with a litany of other federal district court cases specifically involving Defendant — with the instant case, it is clear that Plaintiff has plead a number of state common law claims which parallel the applicable federal requirements with allow Defendant's devices to be eligible for PMA. These claims are predicated upon Defendant's violation of federal laws requiring Defendant to report adverse events associated with off-label uses of its device, as well its misconduct in promoting these off-label uses for its device despite actual or implied knowledge of its relative dangers and risks when compared with traditional bone graft techniques. Defendant consistently failed to report such adverse events to the FDA or even submit a supplemental application seeking approval of the off-label use it was actively promoting by improperly influencing the professional opinions of so-called opinion leaders who vouched for the device's safety and efficacy in cervical spine procedures, despite its sole approval for use in lumbar spinal fusion. Defendant's fraudulent misrepresentations to these opinion leaders are the centerpiece of Plaintiff's Complaint, providing the backbone for the other claims provided in the complaint and comprising the grease which effectively squeezes Plaintiff's claims through the proverbial gap past federal express and implied preemption.

3. Plaintiff Does Not Predicate His Claims on Off-Label Promotion

Defendant mistakenly asserts in its Motion that Plaintiff's claims center around its off-label promotion, which Defendant believes Plaintiff alleges as a violation of state and federal law. In support of its argument, Defendant relies heavily on a number of courts which have weighed in regarding whether off-label promotion is a violation of federal or state law, and whether claims based upon off-label promotion are expressly or impliedly preempted by § 360k. *See, e.g., Brady*, 2014 WI 1377830, at *5 ("the FDCA does not expressly prohibit off-label marketing"); *Schuler v. Medtronic, Inc.*, 2014 WL 988516, at *1 (C.D. Cal. 2014) ("federal law does not bar off-label promotion"); *Dawson v. Medtronic, Inc.*, 2013 WL 4048850, at *6 (D.S.C. 2013) (refusing to "accept Plaintiff's premise that off-label promotion is illegal under the FDCA"); *Caplinger*, 921 F. Supp. 2d at 1219-20, 1224 ("[T]he concept of 'off-label use' is a creature of the FDCA, is defined by the FDCA, and is not part of [state] law."); *Gavin v. Medtronic, Inc.*, 2013 WL 3791612, at *17 (E.D. La. 2013) ("There is no . . . state law claim

premised on off-label promotion."); *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 398378, at *5 (E.D.N.Y. 2008) ("[T]here is no state law equivalent of 'off-label.'"); *Houston*, 957 F. Supp. 2d at 1177-78 (holding that state law claims predicated on off-label promotions are expressly preempted by § 360k(a)); *Hawkins*, 2014 WL 346622, at *10-11 (same). (Def.'s Mot. to Dismiss, at 19-21.)

However, as the Court will notice in the Proposed FAC, the lynchpin of Plaintiff's claims is Defendant's failure to report adverse events associated with off-label use to the FDA in the PMA process, and the resulting breaches of duties to warn Plaintiff and his physician of the dangers associated with off-label use, as well as breaches of warranties afforded under state law. Plaintiff does not make the off-label promotion the centerpiece of his Complaint; rather, the purpose of including Defendant's extensive off-label promotion is to provide evidence to the finder of fact and the Court that Defendant knew of the adverse events associated with off-label use, the relative dangers and risks associated with off-label use in cervical spinal fusion surgery, and failed to provide that information to the FDA in its PMA process, as well as to Plaintiff and his physician in order to make the most informed treatment recommendation. The label on Defendant's device merely warns physicians that "[t]he safety and effectiveness of the inFUSE Bone Graft component . . . implanted at locations other than the lower lumbar spine . . . have not been established," when, in fact, Defendant was on notice that such off-label uses had extreme adverse effects when used in the cervical spine and failed to include this information in its application to the FDA.

Lastly, Defendant alleges that Plaintiff's claim is impliedly preempted and barred pursuant to 21 U.S.C. § 337(a), the FDCA's no-private-right-of-action clause which prohibits any state-law claim seeking to enforce the federal medical device requirements. Again, this argument rests on the misinformed and mistaken grounds that Plaintiff is predicating his claims entirely on Defendant's extensive promotion of off-label uses to opinion leaders and other surgeons. However, Plaintiff does not base his claims upon Defendant's off-label promotion, but rather uses it to provide proof that Defendant knew of the adverse events and dangerous effects implicated in off-label uses, including the use of the device in cervical spinal fusion procedures. Thus, § 337(a) does not apply to preempt or bar Plaintiff's claims because Plaintiff is not expressly seeking to enforce any federal requirement created by the FDCA and its regulations;

rather, Plaintiff utilizes Defendant's failure to inform the FDA, Plaintiff, and his physician as evidence going toward its breach of his duty to warn Plaintiff of the potential dangers of off-label use, its breach of express and implied warranties, and fraudulent omission and concealment regarding these effects in marketing, promoting, and labeling the device to consumers.

Even if this Court finds that Plaintiff's claims use as a basis Defendant's failure to disclose adverse effects, the Supreme Court has found in *Silkwood* v. *Kerr-McGee Corp.*, 464 U. S. 238 (1984), "a virtually irrefutable presumption against implied preemption of private damage remedies predicated on an alleged conflict with a federal remedial scheme." The *Silkwood* Court declined to infer that a federal statutory scheme that affords no alternative means of seeking redress effectively pre-empted traditional state-law remedies. *See Silkwood*, 464 U.S. at 251. concurring opinion in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) — penned by Justices Stevens and Thomas — recognized this absurdity, opining that the harsh pre-emption analysis advanced by the majority opinion in that case surely could not be the intended result of Congress when they created the FDCA. Justices Stevens and Thomas reasoned that "parties injured by fraudulent representations to federal agencies would have no remedy even if recognizing such a remedy would have no adverse consequences upon the operation or integrity of the regulatory process." *Buckman*, 531 U.S. at 355 (Stevens and Thomas, J., concurring).

Thus, Defendant's claim that since Plaintiff is predicating his claim on off-label promotion it is impliedly preempted by statute due to the comprehensive federal regulatory scheme in place for medical devices is inapposite. It mischaracterizes Plaintiff's Complaint, which should be apparent from the Proposed First Amended Complaint. Thus, this Court should deny Defendant's Motion and allow Plaintiff leave to amend his original Complaint to clarify these points and allow Defendant to prepare a more adequate defense.

II. MOTION FOR LEAVE TO AMEND COMPLAINT

Plaintiff respectfully moves the Court, pursuant to Rule 15 of the Federal Rules of Civil Procedure, for leave to file a First Amended Complaint ("FAC"), a copy of which is attached hereto as Exhibit A. The FAC maintains the counts and allegations against the same Defendant, but addresses and cures the deficiencies alluded to in Defendant's Motion to Dismiss, and offers more robust factual support for the claims made therein. Further information has since been discovered, all of which is included in the FAC. Plaintiff respectfully requests this Court grant

leave to amend his Complaint in anticipation of the Court's ruling on Defendant's Motion to Dismiss, such that its procedural deficiency aspects can be easily dispensed with and the Court can narrow its focus on the merits of Plaintiff's prima facie case.

A. LEGAL STANDARD

Pursuant to Federal Rule of Civil Procedure 15(a)(2), "a party may amend its pleading only with the opposing party's written consent or the court's leave. The court should freely give leave when justice so requires." The decision whether to grant leave to amend a pleading is within the sound discretion of the district court. *See Nat'l Serv. Indus., Inc. v. Vafla Corp.*, 694 F. 2d 246, 249 (11th Cir. 1982)). Courts have also recognized that "this discretion is strictly circumscribed by the proviso that 'leave [should] be freely given when justice so requires." *See Gramegna v. Johnson*, 846 F.2d 675, 678 (11th Cir. 1988)). Moreover, it is worth noting that the United States Supreme Court has declared that "this mandate is to be heeded." *Foman v. Davis*, 371 U.S. 178, 182 (1962).

In effect, a justifying reason must be apparent for denial of a motion to amend. *See Moore v. Baker*, 989 F.2d 1129, 1131 (11th Cir. 1993). The law is well-settled that leave to amend a pleading should be denied only where there is evidence of undue delay, bad faith, or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of the amendment. *See Foman*, 371 U.S. at 182.

Thus, "unless a substantial reason exists to deny leave to amend, the discretion of the district court is not broad enough to permit denial." *Shipper v. Eastern Air Lines, Inc.*, 868 F.2d 401, 407 (11th Cir. 1989). The Supreme Court explained that "if the underlying facts or circumstances relied upon by a plaintiff may be a proper source of relief, he ought to be afforded an opportunity to test his claim on the merits." *Foman*, 371 U.S. at 182.

C. ARGUMENT

First, Plaintiff addresses the necessarily interconnected factors of bad faith, undue delay, and prejudicial effect of this Court's analysis in whether to grant Plaintiff's Motion for Leave to Amend.

"One of the most important considerations in determining whether amendment would be prejudicial is the degree to which it would delay the final disposition of the action." *Krumme v.*

WestPoint Stevens Inc., 143 F.3d 71, 88 (2d Cir.), *cert. denied*, 525 U.S. 1041 (1998) (internal quotation omitted). Mere delay, however, unaccompanied by either bad faith or undue prejudice, does not warrant denial of leave to amend. *Block v. First Blood Assocs.*, 988 F.2d at 350 (citing *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981)).

The Second Circuit has made it clear that without a showing of bad faith or prejudice, the mere passage of time since the filing of a complaint provides no reason to deny leave to amend. *See Richard Greenshields Sec., Inc. v. Lau*, 825 F.2d 647, 653 n.6 (2d Cir. 1987); *State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981); *see also, e.g., Abbatiello v. Monsanto Co.*, 571 F. Supp. 2d 548, 553 (S.D.N.Y. 2008); *In re Horizon Cruises Litig.*, 101 F. Supp. 2d 204, 215 (S.D.N.Y. 2000). In fact, leave to amend has been found appropriate even when the request is made well after the close of discovery, up to the eve of trial. *See, e.g., Guzman v. Bevona*, 90 F.3d 641, 649 (2d Cir. 1996); *Hanlin v. Mitchelson*, 794 F.2d 834, 840-41 (2d Cir. 1986).

Granting Plaintiffs' motion for leave to amend will not cause undue prejudice to Defendants as no discovery has taken place. *See State Teachers Ret. Bd. v. Fluor Corp.*, 654 F.2d 843, 856 (2d Cir. 1981) ("This is not a case where the amendment came on the eve of trial and would result in new problems of proof. At the time plaintiffs requested leave to amend, no trial date had been set by the court and no motion for summary judgment had yet been filed by the defendants."); *see AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 725 (2d Cir. 2010) ("Amendment may be prejudicial when, among other things, it would 'require the opponent to expend significant additional resources to conduct discovery and prepare for trial' or 'significantly delay the resolution of the dispute.'").

Whether the non-moving party will be prejudiced by such an amendment is especially important in determining a party's motion to amend. According to the Second Circuit, a court must consider "whether the assertion of the new claim would: (i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." *Block v. First Blood Assocs.*, 988 F.2d 344, 350 (2d Cir. 1993) (citations omitted).

Here, Plaintiff submits that his Motion for Leave to Amend the original Complaint is not borne from notions of bad faith or to create undue delay. In fact, even if there has been delay

leading up to this stage in the case, the delay is not considerable considering that the case is in such an early stage — that is, before the parties have had a chance to exchange discovery in order to fully flesh out the claims outlined in the original complaint. Defendant would in no tangible way be prejudiced by this Court allowing Plaintiff leave to amend his original Complaint, as the amendment would not serve to simply delay the resolution of the case or dry up the residue in Defendant's pocketbooks in a lengthy discovery process and in anticipation of trial.

It is worth noting that the discovery required by Plaintiff's claims should be readily available given the multitude of lawsuits filed against Defendant in the recent past for injuries caused by its Infuse device, most of which involve similar claims and factual circumstances. Plaintiff's Proposed Amended Complaint does not prejudice Defendant because the claims lodged against it essentially remain the same, but contain further supporting facts to assist both the trier of fact and Defendant in more fully understanding the case and the factual circumstances which led to Plaintiff's severe and permanent injuries.

Second, Plaintiff addresses the futility aspect of this Court's analysis in whether to grant Plaintiff leave to amend his original Complaint.

Interestingly enough, the determination whether a proposed amendment is futile is made under the same standard as that used to determine whether a claim would be subject to a motion to dismiss. *See Hampton Bays Connections, Inc. v. Duffy*, 212 F.R.D. 119, 123 (E.D.N.Y. 2003) (citing *A.V. by Versace, Inc. v. Gianni Versace S.p.A.*, 160 F. Supp. 2d 657, 666 (S.D.N.Y. 2001), *overruled on other grounds, Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002)). Essentially, the proposed amended claim must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Instead, it "must allege facts that are not merely consistent with the conclusion that the defendant violated the law, but which actively and plausibly suggest that conclusion." *Port Dock & Stone Corp. v. Oldcastle Ne.*, Inc., 507 F.3d 117, 121 (2d Cir. 2007) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. at 557); *Sengillo v. Valeo Elec. Sys., Inc.*, 536 F. Supp. 2d 310, 312 (W.D.N.Y. 2008) (applying *Bell Atl. Corp.* standard), *aff'd*, 328 F. App'x 39 (2d Cir. 2009).

Furthermore, an amendment is considered futile if the amended pleading would not survive a motion to dismiss, either pursuant to Rule 12 (b)(6) or on some other basis. *Dougherty*

v. Town of North Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 88 (2d Cir. 2002); *McKinney v. Eastman Kodak Co.*, 975 F. Supp. 462, 465 (W.D.N.Y. 1997).

For the reasons discussed above in Plaintiff's Opposition to Defendant's Motion to Dismiss, the amendments made in his Proposed Amended Complaint would not be an exercise in futility. Plaintiff submits that his claims should be permitted to slip between the gap afforded by the federal preclusion provisions of § 360k and that the factual circumstances and claims outlined in the Proposed Amended Complaint are necessary to bolster Plaintiff's case in order to bridge that gap. Given the immense difficulty of meeting federal pleading standards where much of the required information is confidential and only made available at the discovery phase, Plaintiff's attempt at amending his original Complaint only serves to bolster his allegations against Defendant, claims which can only become more compelling as the case moves to the discovery phase and Plaintiff gains access to information which is necessary to try the case. To refuse to allow Plaintiff to amend his original Complaint at this stage would be a miscarriage of justice in that it would effectively give Defendant a procedural windfall in order to defeat Plaintiff's claim before he has had a chance to discover the pertinent information required to successfully try it.

Lastly, Plaintiff asserts that interests of justice and judicial economy would best be served by allowing Plaintiff to set forth proper allegations and proceed on the merits of the case, as opposed to focusing on the rather technical, procedural aspects of federal pleadings. Moreover, as Plaintiff was previously unaware of Defendant's affirmative defense of preemption in light of its failure to file an answer containing that affirmative defense and instead to move this Court to dismiss Plaintiff's claim on that basis alone. Now, having been presented with an affirmative defense, Plaintiff is entitled to attempt to cure the problems identified by Defendant's Motion to Dismiss and any the Court discovers through an amended complaint.

Accordingly, as Plaintiff has demonstrated favorable results of the analyses outlined above, Plaintiff prays for relief in the form of leave to allow him to file the Proposed First Amended Complaint, which is attached as Exhibit A. Thus, in the interest of justice, this Court should grant Plaintiff's motion for leave to file the proposed amended complaint. The granting of this motion is particularly appropriate here, given the clear absence of any substantial reason to deny leave to amend.

III. CONCLUSION

For the foregoing reasons, Plaintiff opposes Defendant's Motion to Dismiss. In addition, Plaintiff requests that the Court grant it leave to file the attached First Amended Complaint.

Respectfully Submitted this 6th day of May, 2015.

Rochester, New York

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EXHIBIT A

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Plaintiff's (Proposed)
First Amended Complaint

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ATTORNEY FOR PLAINTIFF

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

TYLER WOOD, Plaintiff, vs. **MEDTRONIC, INC.,** Defendant.	Case No. 6:14-cv-06298-CJS **(PROPOSED) FIRST AMENDED COMPLAINT** (1) Fraudulent Omission and Concealment (2) Strict Products Liability - Failure to Warn (3) Strict Products Liability - Manufacturing or Design Defect (4) Breach of Implied Warranty (5) Negligence (6) Negligence Per Se

COMES NOW Tyler Wood ("Plaintiff"), by and through his attorney, Thomas J. Rzepka, hereby complains against Medtronic, Inc. ("Defendant"), alleging the following in support of his complaint:

I. INTRODUCTION

1. Plaintiff hereby institutes this Civil Action Complaint against Defendant, revolving around the severe and permanent injuries caused by the spinal stimulating bone graft known as the Infuse® Bone Graft (hereinafter "Infuse®").

2. Infuse® was promoted and sold to be used "off-label" to treat Plaintiff, who required a cervical spine procedure when he was an infant. However, Infuse® is approved by the FDA for lumbar surgery only, a procedure which is performed through the abdomen. The FDA has never approved Infuse® for cervical spine procedures.

3. Due to Defendant's unlawful conduct, thousands of patients nationwide were persuaded to undergo surgeries without being aware of the associated risks. According to reports from the Department of Justice and the FDA investigations, those doctors who persuaded patients like Plaintiff Tyler Wood to undergo cervical spine surgery using Infuse® were, in turn,

persuaded by Medtronic's "opinion leaders" — essentially paid physician promoters — and Medtronic sales representatives, to use the product off-label.

4. In this case, Plaintiff underwent a cervical spine surgery, utilizing Infuse® under the recommendations of his physician, and suffered permanent and irreparable injury as a result of such off-label usage.

A. PLAINTIFF TYLER WOOD

5. Plaintiff was a minor at the time of the incident involved herein, having a date of birth or April 26, 1993.

6. In or about January 2003, Plaintiff underwent his first cervical spinal fusion surgery, in which a titanium rod was inserted to provide stability and assist with fusing his vertebrae. In early 2006, the titanium rod which was inserted in Plaintiff's neck had broken, and fragmented pieces were loose and floating around in his neck.

7. Shortly thereafter, on or about March 14, 2006, Plaintiff underwent a posterior cervical spinal fusion procedure at University of Iowa Hospital, performed by Dr. Arnold Menezes. The vertebrae fused in said procedure were C1 to C3.

8. Infuse® was used in said procedure in order to assist Plaintiff's cervical spinal fusion.

9. To his recollection, Plaintiff had no symptoms immediately following discharge, and returned to the University of Iowa periodically to follow up on the progression of the spinal fusion procedure. Plaintiff was not initially prescribed any medication to treat any side effects or symptoms from the spinal fusion procedure.

10. Plaintiff began to notice side effects from the surgery shortly thereafter, and experiences ongoing and persistent excruciating pain in his neck on a daily basis. The pain is typically worse in the mornings and in cold weather.

11. The use of Infuse® has caused injuries to Plaintiff which are severe and permanent.

12. Plaintiff no longer travels back to the University of Iowa for medical treatment. Instead, Plaintiff has chosen a local orthopaedic surgeon, Dr. Gordon Whitbeck, to provide follow-up care and treat his ongoing side effects from the use of Infuse® in his procedure.

13. Plaintiff continues to see Dr. Whitbeck annually to ensure that the fusion is stable and that there is no ectopic bone growth outside the fusion area.

B. DEFENDANT'S INFUSE® DEVICE

14. Defendant designed and marketed Infuse® for lumbar spine surgery.

15. Infuse® is a bio-engineered bone filling material containing a bone morphogenetic protein ("BMP") which is used to help fuse vertebrae in the lumbar (lower) spine in order to treat degenerative disc disease. Essentially, Infuse® is used as a alternative to traditional bone grafting techniques, which typically use bone from a patient's hip and have side effects such as pain at the grafting site and long recovery.

16. The active ingredient in Infuse® is rhBMP-2, a manufactured version of a protein present in the body that promotes new bone growth. RhBMP-2 has been studied more than any other BMP and has also been approved by the FDA solely for use in lower spinal, tibial fractures, and dental surgeries.

17. Infuse® was approved by the FDA on July 2, 2002, for use only in the lower region of the spine in order to treat degenerative disc disease, and was approved only for anterior surgeries at L4 through S1. Infuse® is also used to fill space needed to place dental implants — a use for which it was FDA-approved on March 9, 2007 — and the repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management.

18. Infuse® is one of Defendant's best selling products. One market analyst has publicly estimated that the product sales equal approximately $815 million for the fiscal year ending in April 2008.

C. DANGERS & EFFICACY OF OFF-LABEL USE

19. Infuse® has never been approved by the FDA for use in any other parts of the body or for use in any other type of procedure — uses typically deemed "off-label." It is important to note that while physicians may use FDA-approved medical devices any way they deem medically necessary, the companies which manufacture those devices are not permitted to promote such off-label uses or pay physicians to promote or perform procedures with them.

20. On July 1, 2008, the FDA issued a Public Health Notification detailing the issues that may arise from off-label use of Infuse® in cervical spine procedures. The FDA made this report based on 38 reports in four years, some of which involved life-threatening and fatal

results. Moreover, the FDA expressed concerns around the reported complications relating to swelling of the neck and throat tissue, which causes difficulty swallowing, breathing, and speaking. The reports made to the FDA also contained many patients who required emergency treatment, including tracheotomies and feeding tube insertions.

21. This Public Health Notification reads: **"Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by the FDA for this use."** *FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion*, issued July 1, 2008 (http://www.fda.gov/cdrh/safety/070108-rhbmp.html) (emphasis in original).

D. DOJ INVESTIGATION REGARDING IMPROPER PROMOTIONAL EFFORTS

22. Companies who design, manufacture, and market devices to be used in medical procedures rely on relationships with surgeons held in high regard in their profession — deemed "Opinion Leaders" — such that the company will pay those surgeons consulting fees, travel expenses, and other monetary perks in exchange for those surgeons to promote the use of their device in not only their practice, but actively encourage other physicians and surgeons to recommend their device to patients or use it exclusively in their practice.

23. Here, Medtronic improperly paid doctors to promote the off-label use of Infuse® in cervical spine procedures despite their actual or implied knowledge that it was no more effective, or, in the alternative, more dangerous, than traditional bone grafting procedures used in spinal fusion.

24. Defendant was named in two qui tam actions in in Federal Court in the Western District of Tennessee, in which the United States alleged that Defendant violated the False Claims Act, 31 U.S.C. 3729, *et seq.*, by paying illegal kickbacks to certain physicians in connection with promoting the off-label use of Infuse® in the cervical spine procedures, resulting in the submission of false or fraudulent claims to federal health care programs. *See United States ex rel. (UNDER SEAL) v. Medtronic, Inc., et al.*, Civil Action N. 02-2709 (W.D. Tenn.), and *United States ex rel. Poteet v. Medtronic, Inc., et al.*, Civil Action No. 03-2979 (W.D. Tenn.).

25. Therein, the Department of Justice alleged that between January 1, 1998 and April 30, 2003, Defendant made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products. These remunerations included: (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks," VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through Defendant's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

26. Thus, the Government concluded that certain payments, services, and remuneration were improper, resulting in the submission of false or fraudulent claims, giving rise to the legal claims plead therein.

27. To settle the case, Medtronic agreed in July 2006 to pay $40 million to the Government under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812. As a result, Defendant and its subsidiary, Medtronic Sofamor Danek USA, Inc., agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Unites and to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

28. Unfortunately, this was not the end of Defendant's off-label marketing activities and related payments. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to Defendant, expressing several concerns regarding the corporate integrity agreement made pursuant to the July 2006 settlement.

29. In relevant part, Senator Kohl's leader reads:

> In [its] letter to the Committee, [Defendant] and its subsidiary both denied that "improper payments were made to physicians in the first place ([Defendant's] agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.'" Consequently, it was with concern that I read recent articles, in the *Wall Street Journal* and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by [Defendant] to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major

> orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. Medtronic's response to the Committee's initial inquiry articulated no specific reasons as to why [Defendant] has yet to voluntarily make the same disclosures.

30. Senator Kohl demanded both documentations of Defendant's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of [Defendant's] physician compensation practices."

31. Furthermore, Senator Kohl requested Defendant explain "the circumstances that led to [Defendant's] former counsel to file suit against the company [alleging improper payments to physicians] and how that matter was subsequently settled."

32. Thereafter, on September 30, 2008, U.S. Senator Charles Grassley sent a strikingly similar letter to Medtronic pertaining to the marketing of Infuse® and allegations of related kickbacks to physicians regarding the sale of the devices. In his letter, Senator Grassley stated:

> Last week, the *Wall Street Journal (WSJ)* reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in."[1] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.

33. Senator Grassley also expressed his concern over *Wall Street Journal* reports "that one of the incentives [Defendant] provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

34. Specifically, Senator Grassley addressed concerns related to Defendant's marketing of Infuse®:

> Fourth, earlier this month the WSJ reported on problems with off-label use of [Defendant's] Infuse®. Infuse® is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that [Defendant] gave payments to

[1] David Armstrong, "Lawsuit Says Medtronic Gave Doctors Array of Perks," *Wall Street Journal*, September 25, 2008.

> physicians, in the form of consulting agreements, as a means of increasing sales of Infuse®. The allegations that [Defendant] has been disguising these consulting agreements as inducements or kickbacks for physicians to use Infuse® are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these reported events.

35. Lastly, Senator Grassley questioned why several lawsuits against Defendant pertaining to Infuse® remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation."

II. JURISDICTION & VENUE

36. Plaintiff alleges an amount in controversy exceeding $75,000, exclusive of interest and costs. Thus, this Court has the requisite jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiff and Defendant.

37. At all relevant times herein, Plaintiff was a resident of the County of Monroe and the State of New York. By contrast, Defendant is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. Defendant is authorized to do business in the State of New York, and was, in fact, doing business in the State of New York.

III. SUMMARY OF ALLEGATIONS

38. Plaintiff Tyler Wood suffered severe and permanent injuries as a direct and proximate result of Defendant's misconduct surrounding the manufacturing, marketing, promoting, advertising, and sale of Infuse®.

39. Plaintiff and his guardians would not have chosen to be treated with Defendant's defective product had they known of or been informed by Defendant of the existing risks associated with using the product in place of a traditional bone graft procedure.

40. At all relevant times herein, the Defendant researched, developed, designed, manufactured, marketed, promoted, advertised, sold, and distributed Infuse® as a Class III prescription medical device — fully named Infuse® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device.

41. Defendant negligently manufactured, marketed, advertised, promoted, sold, and distributed Infuse® as a safe and effective device to be used for procedures involving the cervical spine. Defendant misrepresented the safety of Infuse® as a safe and effective alternative to a traditional bone graft procedure in spine surgery, and further negligently, recklessly, and/or intentionally over-promoted Infuse® to physicians and consumers while attempting to minimize its dangerous side effects involved with off-label cervical spinal procedures.

42. Any warnings Defendant may have issued concerning the dangers of off-label use of Infuse® in the cervical spine were insufficient when considering the totality of Defendant's over-promotion of Infuse® to physicians and consumers alike.

43. At all times relevant herein, Defendant knew or should have known that Infuse® is and was not safe for off-label use, and that its safety and efficacy for use in the cervical spine was unknown altogether, or, in the alternative, known by Medtronic to be unsafe and ineffective.

44. Defendant concealed this information and failed to warn Plaintiff, his guardians, or his physicians, preventing them from making an informed decision about whether to elect to receive alternative treatments or therapies, including a traditional bone graft procedure.

45. Plaintiff, his guardians, and his physicians relied on Defendant's misrepresentations regarding the safety and efficacy of Infuse® when used off-label for cervical spine procedures in place of traditional bone graft procedures. Plaintiff, his guardians, and his physicians were unaware of the risks and side effects, and/or were misled by Defendant as to the true nature or incidence rate of the risks associated with the use of Infuse® in cervical spine surgeries.

46. Defendant expended significant resources in efforts to promote and market Infuse® to physicians nationwide for off-label use in cervical spine procedures. This promotion and marketing of Infuse® as a safe and effective alternative to traditional bone graft procedures caused Plaintiff, his guardians, and his physicians to elect to implant Infuse® in Plaintiff's cervical spine.

47. Had Plaintiff, his guardians, and his physicians known of the dangerous risks and side effects associated with utilizing Infuse® in cervical spine surgery — as well as relied on the affirmative misrepresentations of Defendant regarding its safety and efficacy — they would not have elected to use Infuse® in Plaintiff's surgery.

IV. CLAIMS FOR RELIEF

(1) FRAUDULENT OMISSION & CONCEALMENT

48. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

50. Defendant had a duty to report adverse events associated with off-label uses to the FDA in applying for the premarket approval process. Defendant consistently failed to report such events as they occurred in direct violation of FDA standards, amounting to concealment and fraudulent omission of material information relating to off-label uses. It is this fraudulent omission which provides the basis of Plaintiff's claims, and which parallels Defendant's state law duty to provide such adverse information to Plaintiff and his physician, as detailed below.

51. Furthermore, Defendant had a confidential and special relationship with Plaintiff due to (a) Defendant's vastly superior knowledge of the health and safety risks relating to Infuse®, and (b) Defendant's sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for cervical spine fusion surgery.

52. As a result, Defendant had an affirmative duty to fully and adequately warn Plaintiff and his physician of the true health and safety risks related to the off-label use of Infuse®, and Defendant had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for cervical spine fusion surgery. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and his physician.

53. Misrepresentations made by Defendant about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and his physician the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.

54. In connection with their Infuse® products, Defendants fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiff and his physician, all as alleged herein.

55. Any of the following is sufficient to independently establish Defendant's liability for fraudulent omission and/or concealment:

a. Defendant fraudulently concealed the health and safety hazards, symptoms, constellation of symptoms, diseases, and/or health problems associated with the off-label use of their Infuse® product in the cervical spine;

b. Defendants fraudulently concealed their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label use of Infuse® in cervical spine surgery;

c. Defendants fraudulently concealed information about the known comparative risks and benefits of the use of Infuse® and relative benefits and availability of alternate products, treatments and/or therapies.

56. Defendant knew that Plaintiff and his physician would regard the matters Defendant concealed to be important in determining the course of treatment, including their decision whether or not to use Infuse® in cervical spine surgery.

57. As a direct and proximate result of Defendant's fraudulent concealment and suppression of material health and safety risks relating to Infuse® and of Defendant's dangerous and irresponsible off-label promotion and marketing practices, Plaintiff suffered severe injuries and economic loss, and will continue to suffer from those injuries and economic loss.

58. As the direct, proximate and legal cause and result of Defendant's fraudulent concealment and suppression of material health and safety risks relating to Infuse® and of Defendant's dangerous and irresponsible marketing and promotion practices, Plaintiff has been injured and incurred damages, including and not limited to medical and hospital expenses, and physical and mental pain and suffering.

59. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

60. Defendant's conduct, as alleged above, was malicious, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and as such warrants an award of punitive damages.

61. The foregoing claim runs parallel to the federal requirements and standards provided by the Food and Drug Administration regarding medical devices designed, manufactured, marketed, promoted, and sold by manufacturers. Thus, this claim avoids preemption by the Medical Devices Act and survives as a parallel state action.

(2) STRICT PRODUCTS LIABILITY: FAILURE TO WARN

62. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

63. Defendant had a duty to report adverse events associated with off-label uses to the FDA in applying for the premarket approval process. Not only did Defendant fail to report such events as they occurred — a direct violation of FDA standards — it even failed to warn the consumers of its product of the dangers associated with off-label uses.

64. Defendant had a duty to warn Plaintiff and his physician about the dangers of Infuse® of which they knew, or in the exercise of ordinary care, should have known, at the time Infuse® left Defendant's control. Defendant did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff and his physician of the dangers of its off-label use in cervical surgery.

65. Defendant failed to warn Plaintiff and his physician of the dangers associated with Infuse® when used off-label in cervical spine surgery including, but not limited to, compression of the airway and/or neurological structures in the neck, difficulty swallowing, breathing and speaking, dysphagia, neck and throat swelling, respiratory arrest, and death.

66. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, Plaintiff sustained serious injuries of a personal and pecuniary nature.

67. Plaintiff sustained extreme pain and suffering from the date of his cervical spine surgery with Infuse®.

68. The foregoing claim runs parallel to the federal requirements and standards provided by the Food and Drug Administration regarding medical devices designed, manufactured, marketed, promoted, and sold by manufacturers. Thus, this claim avoids preemption by the Medical Devices Act and survives as a parallel state action.

(3) STRICT PRODUCTS LIABILITY – MANUFACTURING OR DESIGN DEFECT

69. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

70. Defendant's Infuse® device was defectively designed and manufactured at the time that it left Defendant's control.

71. Infuse® was unreasonably dangerous in that it was unsafe when used as it was promoted by Defendant for use in off-label cervical spine surgeries.

72. Infuse® was not manufactured in conformity with the manufacturer's design.

73. Infuse® failed to perform as safely as an ordinary consumer would expect and/or the risk of danger inherent in the design outweighs the benefits of the design.

74. Defendant's unreasonably dangerous and defectively designed and manufactured Infuse® was the direct, legal and proximate cause of Decedent's damages including, but not limited to, medical and hospital expenses, pain and suffering, and economic loss.

75. As a direct and proximate result of Infuse®'s defective design and manufacture, Plaintiff sustained serious injuries of a personal and pecuniary nature.

76. Plaintiff sustained extreme pain and suffering from the date of his cervical spine surgery with Infuse®.

77. The foregoing claim runs parallel to the federal requirements and standards provided by the Food and Drug Administration regarding medical devices designed, manufactured, marketed, promoted, and sold by manufacturers. Thus, this claim avoids preemption by the Medical Devices Act and survives as a parallel state action.

(4) BREACH OF IMPLIED WARRANTY

78. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

79. Defendant's Infuse® product was intentionally designed, manufactured, promoted, distributed and sold to Plaintiff and/or to his physician to be introduced into the human body for use only in certain types of lumbar spine surgeries, and for dental/facial surgeries.

80. Defendant knew, or had reason to know, the particular purpose for which Infuse® would be used and that Plaintiff and/or his physician were relying on Defendant's skill or judgment to select and/or furnish a product suitable for that purpose.

81. Plaintiff and his physician relied on Defendant's skill and/or judgment in deciding to purchase and use Infuse® in his cervical spine surgery.

82. Defendant breached the implied warranties of merchantability and fitness because Defendant's Infuse® product cannot pass without objection in the trade, is unsafe, is not

merchantable, is unfit for its ordinary use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact on the container or label.

83. Defendant's breaches of the warranties of merchantability and fitness was the direct, legal and proximate cause of Plaintiff's damages, including but not limited to medical and hospital expenses and economic loss.

84. As a direct and proximate result of Defendant's breaches of the warranties of merchantability and fitness, Plaintiff sustained serious injuries of a personal and pecuniary nature.

85. Plaintiff sustained extreme pain, suffering, and anguish from the date of her cervical spine surgery with Infuse®.

86. The injuries to Plaintiff were caused solely and wholly by the acts of Defendant without any culpability on behalf of Plaintiff.

87. The foregoing claim runs parallel to the federal requirements and standards provided by the Food and Drug Administration regarding medical devices designed, manufactured, marketed, promoted, and sold by manufacturers. Thus, this claim avoids preemption by the Medical Devices Act and survives as a parallel state action.

(5) NEGLIGENCE

88. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

89. Defendant marketed Infuse® to and for the benefit of Plaintiff, and additionally marketed it to his physician, and Defendant knew or should have known that Plaintiff and his physician would use their product, including for the off-label use of cervical spine fusion.

90. Through the conduct described above, Defendant breached its duty to Plaintiff and his physician.

91. The following sub-paragraphs summarize Defendant's breaches of duties to Plaintiff and his physician and describe categories of acts or omissions constituting breaches of duty by Defendant. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing for the off-label use of cervical spine fusion surgeries;

b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label in cervical spine surgery including, but not limited to, compression of the airway and/or neurological structures in the neck, difficulty swallowing, breathing and speaking, dysphagia, neck and throat swelling, respiratory arrest, and death.

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®;

92. Defendant knew, or should have known, that, due to their failure to exercise reasonable care, Plaintiff and his physician would use and did use Infuse®, to the detriment of Plaintiff's health, safety, and well-being.

93. As the direct, producing, proximate and legal cause and result of Defendant's negligence, Plaintiff suffered severe injuries.

94. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

95. Defendant's conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiff and as such warrants an award of punitive damages.

96. The injuries to Plaintiff were caused solely and wholly by the acts of Defendant without any culpability on behalf of Plaintiff.

(6) NEGLIGENCE PER SE

97. Plaintiff incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

98. Defendant violated applicable federal statutes and regulations relating to medical devices. Plaintiff is a person whom these statutes and regulations were meant to protect.

99. Defendant's violation of these statutes or regulations goes toward a finding of negligence *per se*.

100. Defendant's violation of these statutes or regulations was the direct, producing, proximate and legal cause of Plaintiff's injuries and damages. As the direct, producing and legal

cause and result of Defendant's negligence, Plaintiff was injured and thus incurred damages and losses.

101. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

102. Defendant's conduct, as alleged above, was malicious, intentional, and outrageous and constituted willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such warrants an award of punitive damages.

103. The injuries to Plaintiff were caused solely and wholly by the acts of Defendant without any culpability on behalf of Plaintiff.

104. The foregoing claim runs parallel to the federal requirements and standards provided by the Food and Drug Administration regarding medical devices designed, manufactured, marketed, promoted, and sold by manufacturers. Thus, this claim avoids preemption by the Medical Devices Act and survives as a parallel state action.

V. PRAYER FOR RELIEF

105. WHEREFORE, Plaintiff demands judgment against the Defendant as follows:

1. For compensatory damages and general damages — economic and non-economic — sustained by Plaintiff in an amount to be determined at trial;
2. For punitive and exemplary damages according to proof against Defendant;
3. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees; and
4. For such other and further relief as the Court deems just and proper under the present circumstances.

Respectfully Submitted this 6th day of May, 2015.

Rochester, New York

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